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6 IN THE UNITED STATES DISTRICT COURT
7 FOR THE DISTRICT OF ARIZONA

8 IN RE: Bard IVC Filters Products Liability Litigation, No. MDL 15-02641-PHX DGC

9 ORDER

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12 The Court held a fifth case management conference with the parties on
13 August 23, 2016. In preparation for the conference, the parties provided a joint status
14 report that identified a number of issues for discussion. Doc. 3102. The report noted that
15 the parties disagree on the discoverability of certain electronically stored information
16 (“ESI”) generated by foreign entities (subsidiaries or divisions of Defendant C.R. Bard)
17 that sell IVC filters abroad. Plaintiffs seek discovery of communications between the
18 foreign entities and foreign regulatory bodies regarding the IVC filters at issue in this
19 case. Doc. 3264 at 2. The Court discussed this topic at some length during the status
20 conference on August 23, 2016, and directed the parties to provide focused briefing.
21 Each side has now filed a memorandum addressing this issue. Docs. 3309, 3326. For the
22 reasons set forth below, the Court will deny Plaintiffs’ request for this discovery.
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24 **I. New Legal Standards Governing the Scope of Discovery.**

25 Rule 26(b)(1) of the Federal Rules of Civil Procedure was amended on
26 December 1, 2015. The new rule defines the scope of permissible discovery as follows:

27 Parties may obtain discovery regarding any non-privileged matter that is
28 relevant to any party’s claim or defense and proportional to the needs of the
case, considering the importance of the issues at stake in the action, the
amount in controversy, the party’s access to relevant information, the

1 party's resources, the importance of the discovery in resolving the issues,
 2 and whether the burden and expense of the proposed discovery outweighs
 its likely benefit.

3 Fed. R. Civ. P. 26(b)(1).

4 **A. Relevancy.**

5 To be discoverable under the first part of this test, information must be "relevant
 6 to any party's claim or defense." *Id.* This language has not changed from the previous
 7 version of Rule 26(b)(1).

8 Before the 2015 amendments, Rule 26(b)(1) also provided that inadmissible
 9 evidence was discoverable if it "appears reasonably calculated to lead to the discovery of
 10 admissible evidence." Some courts – and many lawyers – used this language to define
 11 the scope of discovery. *See, e.g., Surfivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625,
 12 635 (9th Cir. 2005) ("Relevant information for purposes of discovery is information
 13 'reasonably calculated to lead to the discovery of admissible evidence.'") (quoting *Brown*
 14 *Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992)).

15 This phrase was eliminated by the 2015 amendments and replaced with a more
 16 direct declaration of the phrase's original intent: "Information within this scope of
 17 discovery need not be admissible in evidence to be discoverable." Fed. R. Civ. P.
 18 26(b)(1). The Advisory Committee on the Federal Rules of Civil Procedure provided this
 19 explanation for the deletion:

20 The former provision for discovery of relevant but inadmissible
 21 information that appears "reasonably calculated to lead to the discovery of
 22 admissible evidence" is also deleted. The phrase has been used by some,
 23 incorrectly, to define the scope of discovery. As the Committee Note to the
 24 2000 amendments observed, use of the "reasonably calculated" phrase to
 25 define the scope of discovery "might swallow any other limitation on the
 scope of discovery." The 2000 amendments sought to prevent such misuse
 by adding the word "relevant" at the beginning of the sentence, making
 clear that "relevant" means within the scope of discovery as defined in this
 subdivision The "reasonably calculated" phrase has continued to
 create problems, however, and is removed by these amendments.

26 Rule 26, Advis. Comm. Notes for 2015 Amends.

27 The 2015 amendments thus eliminated the "reasonably calculated" phrase as a
 28 definition for the scope of permissible discovery. Despite this clear change, many courts

1 continue to use the phrase. Old habits die hard.¹ In this circuit, courts cite two Ninth
 2 Circuit cases – *Survivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir.
 3 2005), and *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992)
 4 – for the proposition that information is relevant for purposes of Rule 26(b)(1) if it is
 5 “reasonably calculated to lead to the discovery of admissible evidence.”² But these cases,
 6 and others like them, simply applied the earlier version of Rule 26(b)(1).

7 Amended Rule 26(b)(1) was adopted pursuant to the Rules Enabling Act, 28
 8 U.S.C. § 2072, et. seq. That statute provides that “[a]ll laws in conflict with such rules
 9 shall be of no further force or effect after such rules have taken effect.” *Id.*, § 2072(b).
 10 Thus, just as a statute could effectively overrule cases applying a former legal standard,
 11 the 2015 amendment effectively abrogated cases applying a prior version of Rule
 12 26(b)(1). The test going forward is whether evidence is “relevant to any party’s claim or
 13 defense,” not whether it is “reasonably calculated to lead to admissible evidence.”

14 B. Proportionality.

15 The 2015 amendments also added proportionality as a requirement for permissible
 16 discovery. Relevancy alone is no longer sufficient – discovery must also be proportional
 17 to the needs of the case. The Advisory Committee Note makes clear, however, that the
 18 amendment does not place the burden of proving proportionality on the party seeking

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 20 ¹ Last month alone, seven cases relied on the “reasonably calculated” language to
 21 define the scope of permissible discovery. *See Fastvdo LLC v. AT&T Mobility LLC*, No.
 22 16-CV-385-H (WVG), 2016 WL 4542747, at *2 (S.D. Cal. Aug. 31, 2016); *Sierra Club*
 23 v. *BNSF Ry. Co.*, No. C13-0967-JCC, 2016 WL 4528452, at *1 (W.D. Wash. Aug. 30,
 24 2016); *Shell v. Ohio Family Rights*, No. 1:15-CV-1757, 2016 WL 4523830, at *2 (N.D.
 25 Ohio Aug. 29, 2016); *Arrow Enter. Computing Sols., Inc. v. BlueAlly, LLC*, No. 5:15-CV-
 26 00037-FL, 2016 WL 4287929, at *1 (E.D.N.C. Aug. 15, 2016); *Ecomission Sols., LLC v.*
 27 *CTS Holdings, Inc.*, No. MISC. 16-1793 (EGS), 2016 WL 4506974, at *1 (D.D.C.
 Aug. 26, 2016); *Clouser v. Golden Gate Nat'l Senior Care, LLC*, No. CV 3:15-33, 2016
 WL 4223755, at *4 (W.D. Pa. Aug. 9, 2016); *Scott Hutchinson Enters., Inc. v. Cranberry*
 Pipeline Corp., No. 3:15-CV-13415, 2016 WL 4203555, at *2 (S.D.W. Va. Aug. 9,
 2016). Several other cases cited the language as though it were still part of Rule 26(b)(1).
See Fairley v. Wal-Mart Stores, Inc., No. CV 15-462, 2016 WL 4418799, at *2 (E.D. La.
 Aug. 19, 2016); *Kuczak v. City of Trotwood, Ohio*, No. 3:13-CV-101, 2016 WL 4500715,
 at *1 (S.D. Ohio Aug. 26, 2016); *Kubik v. Cent. Michigan Univ. Bd. of Trustees*, No. 15-
 CV-12055, 2016 WL 4425174, at *2 (E.D. Mich. Aug. 22, 2016).

28 ² *See Fastvdo*, 2016 WL 4542747, at *2 (quoting *Survivor Media*, 406 F.3d at
 635); *Sierra Club*, 2016 WL 4528452, at *1 (quoting *Brown Bag*, 960 F.2d at 1470).

1 discovery. The amendment “does not change the existing responsibilities of the court and
 2 the parties to consider proportionality, and the change does not place on the party seeking
 3 discovery the burden addressing all proportionality considerations.” Rule 26, Advis.
 4 Comm. Notes for 2015 Amends. Rather, “[t]he parties and the court have a collective
 5 responsibility to consider the proportionality of all discovery and consider it in resolving
 6 discovery disputes.” *Id.*

7 The inquiry to be conducted under the proportionality requirement, therefore,
 8 requires input from both sides. As the Advisory Committee explained:

9 A party claiming undue burden or expense ordinarily has far better
 10 information – perhaps the only information – with respect to that part of the
 11 determination. A party claiming that a request is important to resolve the
 12 issues should be able to explain the ways in which the underlying
 13 information bears on the issues as that party understands them. The court’s
 14 responsibility, using all the information provided by the parties, is to
 15 consider these and all the other factors in reaching a case-specific
 16 determination of the appropriate scope of discovery.

17 *Id.* The Court therefore will look to evidence and arguments from both sides in deciding
 18 whether discovery from the Bard foreign entities is permitted under Rule 26.

19 **II. Analysis.**

20 **A. Relevancy.**

21 From the information provided by the parties, it appears that most of Defendants’
 22 regulatory communications, including communications with foreign regulators, are
 23 generated by Defendants’ United States operations, which have been and continue to be
 24 subject to extensive discovery. Robert Carr, the key Bard witness on this issue, explained
 25 that the relevant Bard division within the United States “handles the regulatory burden”
 26 for a particular product. Doc. 3311-1 at 4. The division supplies “all the required
 27 documentation” to foreign Bard entities, and the foreign entities then share that
 28 information with foreign regulators. *Id.* Some foreign entities have their own regulatory
 staff, but Bard’s United States operations “supply all the pertinent information, answer all
 the questions. They provide the documentation and translations back and forth.” *Id.* at
 11.

1 Carr further explained that there are regulatory persons on every Bard product
 2 development team, and that “they determine the potential regulatory pathway for a
 3 product being developed early on.” *Id.* at 13. “[T]hroughout the project, they identify
 4 the required standards that need to be met in countries that we know we’re going to go to,
 5 because testing requirements are different in different countries.” *Id.* at 14. “And then at
 6 the end of the project they would put together the supporting documentation to allow
 7 themselves to file in America and . . . the other international regulatory groups to file in
 8 their particular countries using our data. And they would liaise with them throughout that
 9 approval process globally.” *Id.* at 14.

10 Documents submitted by the parties support Bard’s assertion that regulatory
 11 communications are largely controlled from within the United States. For example,
 12 Exhibit F to Defendants’ memorandum is an email chain showing Bard employees within
 13 the United States compiling information to respond to inquiries made by a regulator in
 14 Great Britain. Doc. 3313-7.

15 It also appears, however, that employees in foreign entities sometimes engage in
 16 their own communications with foreign regulators. Mr. Carr provided this testimony
 17 about when Bard’s foreign personnel could have communications with foreign regulators
 18 that are different from the communications prepared in the United States:

19 Q. There’s not a single place where they would be different?

20 A. If the indication for use, which is a regulatory term, defines how and
 21 where a product can be used, how a filter can be used, if it happens
 22 to have a different indication for use in a different country, then
 that’s possible. And so they would be able to change that
 information. Japan is a common example of that.

23 Q. Okay.

24 A. They will change wording and things like that, that’s based on the
 Japanese regulatory approval, not necessarily marketing effort.

25 Q. Sure. They have to get a change in an IFU approved by BPV or
 C.R. Bard before they can do it?

26 A. No, they approve it at their level.

27
 28 Doc. 3266 at 10-11.

1 This exchange suggests that employees in foreign Bard entities at least sometimes
2 communicate with foreign regulators on their own. This fact is confirmed by Exhibit 4 to
3 Plaintiffs' memorandum. It is a communication from David Marshall, an employee of
4 Bard in Great Britain, recounting communications he had with British regulators
5 regarding Bard filters. Doc. 3266 at 13.

6 For purposes of this discovery dispute, the Court concludes that most of the
7 communications with foreign regulators originate in the United States and thus will be
8 captured by the ESI searches currently underway. There do appear, however, to be some
9 communications that originate abroad and may not be captured in the current searches.

10 The Court also finds, however, that the relevancy of these communications is
11 uncertain for at least two reasons. First, there are no Plaintiffs in this MDL from foreign
12 countries. All plaintiffs received their Bard filters and allegedly were injured in the
13 United States. Second, Plaintiffs seek communications with foreign regulators for a
14 narrow purpose – to determine if any of those communications have been inconsistent
15 with Defendants' communications with American regulators. It is inconsistency that
16 Plaintiff's seek to discover.

17 Courts generally recognize that relevancy for purposes of discovery is broader
18 than relevancy for purposes of trial. Even still, the Court concludes that the discovery
19 sought by Plaintiffs is only marginally relevant. With no foreign-based Plaintiffs, and
20 mere conjecture that communications between foreign entities and foreign regulators
21 might be inconsistent with Defendants' communications with American regulators, the
22 discovery appears to be only potentially relevant – more hope than likelihood.

23 **B. Proportionality.**

24 Rule 26(b)(1) identifies several factors to be considered in addressing
25 proportionality. Plaintiffs have addressed some of those factors in the evidence cited
26 above. The "importance of the discovery in resolving the issues," as the Court has
27 explained, appears marginal. The parties "relative access to relevant information" favors
28 Plaintiffs, but only in Defendants' possession of possibly relevant information.

1 Defendants argue that the burden or expense of the proposed discovery outweighs
2 its likely benefit, and they provide some specifics. They note that Bard has entities in
3 Canada, Korea, Australia, India, Singapore, Malaysia, Italy, Ireland, the United
4 Kingdom, Denmark, the Netherlands, Sweden, Norway, Finland, Mexico, Chile, Brazil,
5 and China. Doc. 3309 at 6 n.6. Plaintiffs seek discovery of all communications these
6 entities have had with foreign regulatory authorities involving all Bard IVC filters since
7 2003. *Id.* To comply with Plaintiffs' requests, Defendants assert that they would be
8 required to identify the applicable custodians from these foreign entities for the last 13
9 years, collect ESI from these custodians, and search for and identify communications
10 with foreign regulators. The Court is persuaded by these specifics that the burden of this
11 foreign discovery would be substantial.

12 Plaintiffs are engaging in substantial discovery with respect to Defendants'
13 communications with American regulators, including extensive ESI searches and
14 depositions of relevant witnesses. This discovery should capture communications with
15 foreign regulators that originate in the United States, as most appear to. The Court
16 concludes that the burden and expense of searching ESI from 18 foreign entities over a
17 13-year period outweighs the benefit of the proposed discovery – a mere possibility of
18 finding a foreign communications inconsistent with United States communication.

19 Because the proposed discovery is not proportional to the needs of the case
20 considering the factors set forth in Rule 26(b)(1), the Court concludes that Defendants
21 need not search the ESI of foreign Bard entities for communications with foreign
22 regulators.

23 Dated this 16th day of September, 2016.
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David G. Campbell
United States District Judge